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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,045	11/03/2000	Julie Straub	ACU 109 DIV(2)	7016

7590 04/16/2003  
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EXAMINER

WEBMAN, EDWARD J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 04/16/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

89/706045

Applicant(s)

STRANB

Examiner

WESMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 12/12/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 23-35 is/are pending in the application.
- ☐ Of the above claim(s) 26-28, 30-32 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 23-25, 29, 33-35 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_.

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 2-4
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1617

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23-25, 29, 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Gombotz et al.

Gombotz et al teach microspheres made by a process comprising dissolving an active to which is added a surfactant, after which the solvent is removed (Example I, column 11). Addition of Pore formers is disclosed (column 9, lines 51-55). Addition of sucrose is specified (column 9, line 65). An aqueous injection vehicle is disclosed (column 15, lines 49-50). Microspheres as small as one micron are specified (column 8, line 25).

Parenteral, including subcutaneous delivery is disclosed (Abstracts).

As to the claimed drug particle size, it must be within the size of the microsphere within which it is contained. As to the claimed drug particle TAP density and surface area they must be possessed by the Gombotz et al composition in view of the presence of a pore former.

Applicants argue rapid release, citing figures 2 and 3. However, figure 6, particularly example 15D, demonstrates controlled release over two hours.

Claims 23-25, 29, 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Bernstein et al.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Bernstein et al. Teach microparticles comprising an active (abstract). Phosphatidyl choline (lecithin) is disclosed (column 5 line 41). See spec, page 14 line 25. A pore-forming agent is specified (column 7 lines 49-58). 6-micron particles are disclosed (column 10 lines 43-44). Intravascular administration is specified (column 9 line 51).

The argument regarding TAP density and surface area in the rejection over Gombotz et al. is incorporated herein as applied to Bernstein et al.

No claims allowed.

EP 655237, in German, cited on the PTO 1449 submitted with the IDS of paper # 3, filed 1/25/01, was not considered because the international search report cited in the IDS is not of record.

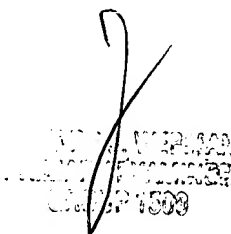
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday-Friday 9am-5pm.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on 305-1877. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234.

Webman/tgd  
March 25, 2003

A handwritten signature, possibly 'J', is written over a rectangular official stamp. The stamp contains the text 'U.S. PATENT AND TRADEMARK OFFICE' and 'MAR 25 2003'.